

JUN - 1 2001



SeQual Technologies Inc.

11436 Sorrento Valley Rd. • San Diego, CA 92121 • 858/558-0202 • FAX 858/558-1915

510(k) SUMMARY

Submitter's Name: SeQual Technologies Inc.

Address: 11436 Sorrento Valley Road
San Diego, CA 92121

Phone: (858) 558-0202 **FAX:** (858) 558-1915

Contact: Ron Hall, Director of Quality Assurance

Date of Summary: November 02, 2000

Name of Device: Model 6400-OM Oxygen Concentrator

Classification Name: Portable Oxygen Generator

Legally Marketed Device to Which Substantial Equivalency Is Claimed:

DYNOTEC (SeQual) Model 6232OM Oxygen Concentrators.

Description of Device:

The SeQual Oxygen Concentrator is a 5-liter per minute oxygen concentrator that is of the pressure swing adsorption (PSA) type. The pneumatic system consists of 5 major components: inlet filtration, air compressor and heat exchanger, synthetic Zeolite molecular sieve beds and distribution valve module, outlet filtration, and flow meter.

The electrical system consists of AC power distribution to the air compressor and a motor with gear reduction used to drive the distribution valve. The unit is double insulated and uses a two-conductor power cable. Device monitoring circuits are included that monitor oxygen concentration. In the event of a malfunction, the unit will shut down and activate visual and audio alarms.

Intended Use:

An oxygen concentrator is a device that draws in normal air and produces an oxygen-enriched output. The air we encounter in nature is a mixture of roughly 78% nitrogen, 21% oxygen, and 1% other trace gases. The SeQual oxygen concentrator is a device that separates the nitrogen from air, producing an output of approximately 90-95% oxygen. The unit is designed to continuously supply supplemental oxygen. It is not intended for life supporting applications.

Technological Characteristics compared to predicate device

The Model 6400-OM and Model 6323OM Oxygen Concentrators have the same general design and incorporate similar technologies, materials, energy sources, and components with the exception that the Model 6400-OM uses software to monitor the oxygen flow.

The primary function of the Model 6400-OM is the same as the Model 6323OM, to provide oxygen for respiratory therapy. The technological characteristics of the devices are basically the same and raise no new questions of safety and effectiveness. SeQual concludes that the Model 6400-OM is substantially equivalent to the Model 6323OM in producing oxygen.

Nonclinical Tests and Results

Standard	Performance Tests	Result
ISO 8359:1996	Excessive Temperatures (Section 7.1)	Passed
ISO 8359:1996	Fire Prevention (Section 7.2)	Passed
ISO 8359:1996	Accuracy of Operating Data (Section 8.1)	Passed
ISO 8359:1996	Protection Against Hazardous Output (Section 8.2)	Passed
	Mechanical Tests	
EN 60601-1:1990+A1:1992+A2:1995	Drop Test (Section 21.6)	Passed
IEC 68-2-34	Random Vibration Test	Passed
	Environmental Tests	
EN 60601-1:1990+A1:1992+A2:1995	Transport and Storage (Section 10.1)	Passed
EN 60601-1:1990+A1:1992+A2:1995	Operation (Section 10.2)	Passed
	Electrical Tests	
EN 60601-1:1990+A1:1992+A2:1995 US Deviations to EN 60601-1(UL2601)	All Requirements of Medical Electrical Equipment.	Passed
	Software Tests	
IEC 601-1-4	Reference "Integra Digital PCA Software Test Report" and Integra Digital PCA Software Regression Test Report" (Section 12)	Passed

SUMMARY OF TEST RESULTS

The units under test passed all tests and demonstrated the ability to operate within specified limits of mechanical stress, electrical stress, temperature, pressure, humidity, conditions of transportation and storage, or certain combinations of these conditions.

Product performance specifications and features were validated.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Ron Hall
SeQual Technologies Inc.
11436 Sorrento Valley Road
San Diego, CA 92121

Re: K003472
Integra Oxygen Concentrator Model 6400
Regulation Number: 868.5440
Regulatory Class: II (two)
Product Code: CAW
Dated: March 6, 2001
Received: March 8, 2001

Dear Mr. Hall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

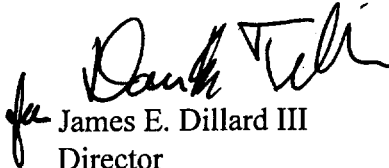
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further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

The image shows a handwritten signature in black ink, which appears to read "James E. Dillard III". The signature is written in a cursive, flowing style.

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: SeQual Technologies Inc.

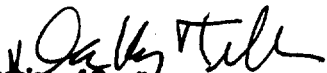
510(k) Number (if known): K003472

Device Name: Model 6400-OM Integra™ Oxygen Concentrators

Indications For Use:

The Integra™ Oxygen Concentrators are indicated for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities.

Prescription legend required.


Division of Cardiovascular & Respiratory Devices
510(k) Number K003472

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)